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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,010	02/28/2002	Toru Nishihara	8279.359USWO	5759
23552	7590	05/26/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			KOSAR, ANDREW D	
			ART UNIT	PAPER NUMBER

1654

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,010	NISHIHARA ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/3/02 and 1/7/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-17 are pending and were examined on the merits.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on June 28, 2001. It is noted, however, that applicant has not filed a certified copy of the JAPAN 200-195804 application as required by 35 U.S.C. 119(b).

Abstract

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

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The abstract of the disclosure is objected to because it recites reference to the merits of the invention (i.e.- useful in the prevention, amelioration or treatment of diseases and disorders of the eye) and contains errors from translation that render the abstract confusing. Correction is required. See MPEP § 608.01(b).

Specification

The disclosure is objected to because of the following informalities: The proper use of the articles “a”, “an”, and “the” should be corrected throughout the specification. Additionally, proper use of plurals should be checked (i.e.- tear vs. tears). Appropriate correction is required.

Claim Objections

Claim 6 is objected to because of the following informalities: The claim recites improper Markush group language. Appropriate language would be, “...selected from the group consisting of A, B, C and D.” Correction is required.

Claim 8 is objected to because of the following informalities: A blank line exists in the claim between the words “the” and “oxygen.” Appropriate correction is required.

Claim 9 is objected to because of the following informalities: A typographical error exists in the third line of the claim, which reads, “...impermeable of less permeable to oxygen....” The examiner has determined that the intended word for clarity of the claim should be “or”, as recited in the similar statement of line two of said claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-⁵~~6~~, 11, 12, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "enriched" in claim 1 is a relative term which renders the claim indefinite. The term "enriched" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The Examiner is unable to determine to what extent the oxygen of Claim 1 has been enriched in view of the claim and/or specification.

The term "sufficient" in claim 2 is a relative term which renders the claim indefinite. The term "sufficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The Examiner is unable to determine what constitutes a sufficient amount of dissolved oxygen in view of the claim and/or specification.

Claim 2 is being indefinite in that it fails to point out what is included or excluded by the claim language. The use of "and/or" in the claim renders the Examiner unable to determine what is the claimed invention.

Claim 3 is indefinite in that it fails to point out what is included or excluded by the claim language. The use of "and/or" is the claim renders the Examiner unable to determine what is the claimed invention.

Claim 4 is indefinite in that it fails to point out what is included or excluded by the claim language. The use of "and/or" is the claim renders the Examiner unable to determine what is the claimed invention.

Claim 5 is indefinite in that it both fails to identify what is included or excluded by the claim language, "...wherein the content of oxygen is at least 90% of the saturated dissolved oxygen...." The claim language is confusing and it is unclear as to the content of oxygen needed within the claim.

The term "less" in claims 11, 12, and 14 is a relative term which renders the claims indefinite. The term "less" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The Examiner cannot sufficiently determine the term "less" as it pertains to oxygen permeability in view of the claims and/or specification.

Claim 14 recites the limitation "...the package...or...the container..." in the 2nd line of said claim. There is insufficient antecedent basis for "the container" in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, and 10-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Klomann (DE4317078, 24-November-1994) in light of American Heritage Dictionary of the English Language: 4th edition, 2000*.

Claim 1 is anticipated by Klomann who teaches artificial tear fluids can obtain a “maximally possible high enrichment with oxygen or oxygenation (e.g., 50 mg of O₂ per liter).” (English Translation Page 2, 3rd paragraph)

Because the term ‘sufficient’ is not specifically defined in the specification, and the Examiner has given this term its broadest interpretation within reason, Claim 2 is anticipated by Klomann who teaches that the concentration of oxygen present in the ophthalmic solution (i.e.-“artificial tears”) is sufficient to treat an ophthalmological disease which is caused by oxygen deficiency, exemplified as conjunctiva of the eyeball. (Claims 1 and 2)

Claim 3 is anticipated by Klomann who teaches an oxygen concentration of, i.e.- 50 mg O₂/liter, and that the concentration is sufficient to treat an ophthalmological disease. (Claim 2)

Claim 4 is anticipated by Klomann who teaches an oxygen concentration of, e.g., 50 mg O₂/liter. (Claim 2)

* This reference is cited merely to relay an inherent property and is not used as the basis for rejection, per se.

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Because Claim 5 is indefinite, and the Examiner has given the description of the "oxygen content" its broadest interpretation within reason, Claim 5 is anticipated by Klomann who teaches that a concentration of oxygen which has maximal high enrichment. (Page 2, paragraph 3) It is deemed that maximal high enrichment means saturated. The content of the oxygen in the saturated solution will be, by default, at least 90%.

Claim 6 is anticipated by Klomann who teaches the use of the recited ophthalmic solution as eye drops. (English Translation Page 4, 2nd paragraph)

Claim 10 is anticipated by Klomann who teaches the use of Ringer's solution as a suitable mode of oxygen delivery. (Page 3, last paragraph)

Ringer's Solution, as evidenced by American Heritage Dictionary of the English Language^{*}, comprises inorganic salts and is defined as:

An aqueous solution of the chlorides of sodium, potassium, and calcium that is isotonic to animal tissue and is used topically as a physiological saline and, in experiments, to bathe animal tissues.

Claims 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Klomann who teaches an oxygen-enriched ophthalmic composition (Claim 2).

Claims 11-15 are composition claims directed towards an ophthalmic composition and recite the same ophthalmic composition of claim 1. Methods of use (i.e.- methods of storing, recited as "...which is stored in...") and description of the storage container do not further limit the composition. The composition of the packaging is not central to the claimed invention (the ophthalmic composition) and the ophthalmic

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composition stored in any manner would anticipate any alternative packaging, in so far as it does not materially affect the composition.

Further, the MPEP states:

Recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim 11 is anticipated by Klomann who teaches the use of a polyethylene drip vial. (Claim 2)

Claim 15 is anticipated by Klomann which teaches the use of a drop vial which is considered to be a "unit dose container". (Page 4, 2nd, for example)

Claim 16 is anticipated by Klomann who teaches a method for wet therapy for eye patients, suffering from lack of oxygen. Specifically, Klomann teaches treatment of conjunctivitis which is a "corneal infiltration" and a "corneal endothelial disorder". (Claim 1, for example)

Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Haidt (S.J. Haidt US 4,452,818; 5-June-1984) who teaches the oxygen carrying properties of perfluorocarbons, an oxygen carrier. (Claim 1)

It has been deemed that perfluorocarbons of Haidt could have produced the composition of Claim 1 in the pending Application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, and 10-17 are rejected under 35 U.S.C. 103(a) as being obvious over Klomann (DE4317078, 24-November-1994) in view of Haidt (S.J. Haidt US 4,452,818; 5-June-1984

The teachings of Klomann were discussed previously. Klomann does not teach the use of oxygen donors/carriers.

Claims 7 and 8 are obvious because Haidt teaches the use of perfluorocarbons, and substituted derivatives thereof, as (1) useful as a therapeutic agent or vehicle in

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extraocular ophthalmic preparations (Column 3, line 10), (2) where said perfluorocarbons have high diffusion properties for oxygen (column 3, line 65), and (3) where said perfluorocarbons can be employed in corneal epithelial disease (column 4, line 3) or (4) treating dry eyes and tear abnormalities (column 7, line 52). Haidt further teaches a method for treating the eyes and protection to the surface of the eyes by topically administering a perfluorocarbon composition which has oxygen carrying properties (Claim 1, for example).

It would have been obvious to one of ordinary skill in the art to combine the oxygen carrying properties of the perfluorocarbon in Haidt with the oxygen enriching method in Klomann in order to achieve the highest concentration of oxygen carrying capacity for a more effective method of treatment for ophthalmologic diseases of the eye resulting from oxygen deficiency.

Claims 1-6, and 9-16 are rejected under 35 U.S.C. 103(a) as being obvious over Klomann (DE4317078, 24-November-1994) in view of Huth (S.W. Huth US 5,389,383; 14-February-1995).

The teachings of Klomann were discussed previously. Klomann does not teach the use of oxygen donors/carriers, such as porphyrins and related polymers.

Claim 9 is obvious because Huth teaches a method of preventing or treating hypoxia-associated ocular complications through administration of a heme oxygenase inducer (column 3, line 50). Huth defines the heme oxygenase inducer as any

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compound known to induce heme oxygenase in vivo, exemplified as heme derivates, porphyrins and porphyrin derivatives.

It would have been obvious to one of ordinary skill in the art to combine the oxygen carrying properties of the porphyrins in Huth with the oxygen enriching method in Kломann in order to maximize the capacity of oxygen in the therapeutic composition. Further one would be motivated to create a therapeutic that could be degraded naturally by such enzymes as heme oxygenase, which is both endogenous to the eye, and could liberate porphyrin bound oxygen.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571)272-0961. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

Andrew D. Kosar
18 May 2004

A handwritten signature in black ink, appearing to read 'Patricia Leith', with a large, stylized initial 'P'.

**PATRICIA LEITH
PRIMARY EXAMINER**